SUMMIT 375 GEL ALCOHOL HAND SANITIZER- ethyl alcohol 70% gel
Dyno Manufacturing

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Summit 375 Gel Alcohol Hand Sanitizer

Active Ingredient

Ethyl Alcohol 70%

Purpose

Antiseptic

Uses

Hand Sanitizer to help reduce bacteria on the skin that potentially can cause disease. For use when soap and water are not available

Warnings

For external use only. FLAMMABLE. Keep away from heat or flame

Do not use

In children less than 2 months of age

On open skin wounds

When using this product

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Place enough product on hands to cover all surfaces. Rub hands together until dry.

Supervise children under 6 years of age when using this product to avoid swallowing.

Other Information

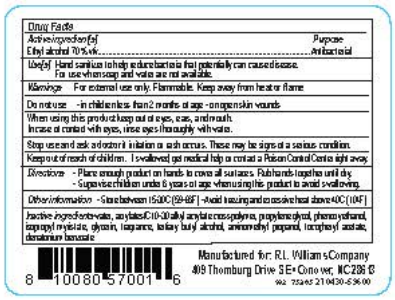
-Store between 15-30C (59-86F).

-Avoid freezing and excessive heat above 40C (104F)

Inactive Ingredients

Water, Acrylates/C10-30 alkyl acrylate crosspolymer, propylene glycol, phenoxyethanol,isopropyl myristate, glycerin, fragrance, Tertiary Butyl Alcohol, aminomethyl propanol, tocopheryl acetate, Denatonium Benzoate

Summit 375 Gel Alcohol Hand Sanitizer



SUMMIT 375 GEL ALCOHOL HAND SANITIZER

ethyl alcohol 70% gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:79532-014
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	595 mL in 850 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL 1,2-DISTEARATE (UNII: T65PN3O37H)	

AMINOMETHYLPROPANOL (PERFLUORO-C6-C12 ETHYL)PHOSPHATE (UNII: QCD5R22RNT)	
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)	
WATER (UNII: 059QF0KO0R)	
.ALPHA.-TOCOPHEROL, DL- (UNII: 7QWA1RIO01)	
DENATONIUM BENZOATE (UNII: 4YK5Z54AT2)	
TERT-BUTYL ALCOHOL (UNII: MD83SFE959)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79532-014-85	850 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	04/01/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/01/2021	

Labeler - Dyno Manufacturing (015718256)

Registrant - Dyno Manufacturing (015718256)

Revised: 5/2021 Dyno Manufacturing